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Attn: TSCA Section 8(e)
U.S. Environmental Protection Agency
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Ladies and Gentlemen:

Subject: Supplemental information regarding prior TSCA Section 8(e) submission – Preliminary results from a cancer incidence study of employees assigned to a BASF Corporation former chemical manufacturing unit in Geismar, LA that ceased operations in 1987 (EPA Control number: 8EHQ-02-15135)

In 2001, BASF Corporation undertook a preliminary cancer incidence and mortality study in response to employee and management concerns about what appeared to be an unusual number of cancer cases. The cases had occurred during the preceding several years among employees who had previously been assigned to a multi-step chemical manufacturing unit producing bentazon (CAS# 25057-89-0). This unit was operated only between 1979 and 1987.

The study included a review of exposure incidents reported to the Medical Department. This was undertaken to characterize the patterns of acute exposures occurring in the unit. The most frequently reported exposures were to phosgene, dimethylcyclohexylamine (DMCA), chlorobenzene, isopropylamidossulfonylchloride (IPS) and IPS residues, thionyl chloride, sulfuric acid, sodium hydroxide, hydrochloric acid, ethylene dichloride, and anthranilic acid. These chemicals were either raw materials in the process or process intermediates. Exposure incident rates were highest during 1979 and were higher for jobs classified as having a high likelihood of contact with process chemicals. There was only one reported exposure to bentazon during the 8 years of operation and that was to the crude product before neutralization.

The findings of the preliminary investigation were submitted to the U.S. Environmental Protection Agency in 2002 in the form of a TSCA Section 8(e) submission (EPA Control number: 8EHQ-02-15135). We are now providing supplemental information obtained based on updating the available mortality and cancer occurrence information among former bentazon unit employees. The previous submission covered the period from 1979 to 2001. The current submission covers the period from 1979 to 2003 and includes the results of having interviewed 120 left or retired employees or their spouses during 2003 and 2004.

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Using multiple record sources, 251 employees were identified who had been assigned to the bentazon unit for 3+ months during its period of operation from 1979-87. The net increase of 7 employees from the prior report is based on information obtained in conversations or interviews with employees following presentations of the previous study results and corroborated through other records.

Among unit employees, there were fewer deaths observed than expected through 2003 (29 observed compared to 34.1 expected deaths based on comparable age- and gender-specific death rates for the U.S. population). There were also fewer observed than expected deaths for employees who worked for 1+ years in job assignments with a high likelihood of daily process contact (17 observed compared to 20.1 expected deaths) and among those employees assigned to the unit throughout its first year of operation (10 observed versus 14.1 expected deaths).

The cancer incidence findings were similar to those observed in the prior study with 17 new cancer cases identified compared to 14.6 new expected cases. Combining the initial study results with the updated results, there were 31 observed versus 22.9 expected cancer cases. Cancer cases have been ascertained through self-report by employees or their spouses, and through death certificates. Expected cancer incidence cases were calculated based on age-, gender- and race-specific cancer incidence rates for South Louisiana as provided by the Louisiana Tumor Registry. Non-melanoma skin cancers were excluded from the comparisons because these data are not available through the tumor registry and may be less reliably reported. The cancer incidence rates for South Louisiana were available only through the year 2000, whereas the experience for this cohort was tracked through 2003.

By type, there were 8 digestive system cancers (4.6 expected cases), 5 of which were due to colorectal cancer (2.6 expected), 2 respiratory cancers (5.7 expected), 11 prostate cancers (5.0 expected), 2 urinary system cancers (1.9 cases expected), 3 lymphatic and hematopoietic tissue cancers (1.9 cases expected) and 5 other cancers (3.8 cases expected). The lower limit of the 95% confidence interval (CI) for the standardized incidence ratio (SIR) exceeded 1.0 only for prostate cancer (SIR = 2.2; 95 CI: 1.1 – 3.9).

Overall cancer incidence did not vary significantly among production compared to maintenance and service employees. There were 14 observed versus 9.0 expected cases among production employees and 17 observed versus 13.9 expected cases among maintenance and service employees. Similarly, cancer incidence did not vary significantly by duration of assignment in jobs with a high likelihood of daily process contact. For the <1 year group there were 11 observed versus 9.2 expected cases and for the 1+ years group there were 20 observed versus 13.7 expected cases. There was variability with respect to having worked in the unit during all of 1979. Among men assigned to the unit for the full year of 1979, there were 20 observed versus 9.5 expected cancer cases, whereas among



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men, who did not work at all during 1979 or for only part of the year, there were 11 observed versus 13.3 expected cases.

The SIR among men assigned to the unit throughout its first year of operation was 2.1, (95% CI: 1.3- 3.3). Thirteen of the 20 cancers were either prostate (9) or digestive system (4) cancers. Annual medical examinations provided to site employees since the 1980s may have contributed to the detection of more cancer cases than would be seen in the corresponding general population. In this study, 8 of the 16 cancers reported among active employees were referred for diagnostic work-up based on annual medical examination findings. Our program has included digital rectal examinations since 1980 and routine PSA testing for men age 50 and above since 1994. Three of the nine prostate cancers among men assigned to the unit throughout 1979 were referred for work-up based on examination findings from the on-site, company-sponsored medical program. Increased awareness of cancer screening may have also contributed to enhanced screening among former employees. Thus, the medical examination program and increased cancer awareness may have contributed to the detection of cancer cases at earlier ages than would be seen in the general population.

No specific agents were identified within the chemical manufacturing process that could account for the observed findings and no cancer cases were identified among 17 men whose job tasks specifically involved final product handling. The final manufactured product, bentazon, has been extensively tested for registration and reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and is not implicated as a suspect causative agent.

Please note that this letter does not contain confidential business information. Any further technical questions should be addressed directly to our Corporate Epidemiologist, Gerald Ott, Ph.D., at Rockaway, NJ (Telephone: 973-895-8023).

Sincerely,

A handwritten signature in cursive script that reads "Sree L. Jasti".

Sree L. Jasti, Ph.D.

Product Regulatory Center of Excellence
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